UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PFIZER INC, ROBERT JARVIK, M.D., JARVIK HEART, INC., Plaintiffs, v. MATHEW I. GELFAND, M.D., Defendant.	x : : : : : : : : : : x	Civil Action No. 08 Civ. 2018 (LAK) (JCF) ECF case

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION TO DISMISS DEFENDANT'S COUNTERCLAIMS

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I. NATURE AND STAGE OF THE PROCEEDING

This is an action by Pfizer Inc ("Pfizer"), Robert Jarvik, M.D. ("Dr. Jarvik"), and Jarvik Heart, Inc. ("JHI"), (collectively referred to as "Plaintiffs") against Mathew I. Gelfand, M.D. ("Gelfand" or "Defendant"), based upon a Complaint for a declaratory judgment of non-infringement, invalidity and unenforceability of United States Patent No. 5,837,688 ("the '688 patent").

Gelfand erroneously failed to answer Plaintiffs' Complaint and sought to dismiss it, precipitating needless motion practice. The Court denied Gelfand's motion to dismiss the Complaint on April 18, 2008 [D.I. 18]. Gelfand finally filed his Answer and Counterclaims [D.I. 19], on April 23, 2008.[1]

Plaintiffs now move pursuant to Fed. R. Civ. P. 12(b)(6) to dismiss Gelfand's Counterclaims for failure to state a claim upon which relief may be granted. This is Plaintiffs' Memorandum of Law in Support of their Motion to Dismiss Defendant's Counterclaims.

II. SUMMARY OF ARGUMENT

1. Gelfand's '688 patent claims only methods of administering a drug. Gelfand's Counterclaim does not allege that any of the Plaintiffs have performed any of the claimed methods. There is no legally viable claim for direct infringement (35 U.S.C. § 271(a)).

2. Gelfand has sued JHI but has failed to allege any action by JHI that constitutes infringement. There is no legally viable claim alleged for infringement by JHI (35 U.S.C. § 271(all subsections)).

[1] For brevity and clarity, this brief eschews the use of the terms "counterclaim-plaintiff" and "counterclaim-defendants" in favor of the individual party names or "Plaintiffs" when referring to Pfizer Inc, Dr. Jarvik and JHI collectively.

3. Gelfand has failed to allege that Dr. Jarvik had knowledge of the '688 patent such that he could be charged with infringement by knowingly inducing others to infringe. Gelfand has failed to allege a legally viable claim against Dr. Jarvik for active inducement (35 U.S.C. § 271(b)).

4. Gelfand alleges infringement under the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2). Gelfand has failed to allege and cannot allege the necessary prerequisites for such a claim – he cannot invoke 35 U.S.C. § 271(e)(2) as his patent does not relate to a drug for which he has obtained FDA marketing approval and Pfizer's FDA approvals for Lipitor® and Caduet® are not embraced by 35 U.S.C. § 271(e)(2). For these reasons, Gelfand's counterclaim fails to state a claim for direct infringement under 35 U.S.C. § 271(e)(2).

Therefore, all claims against Dr. Jarvik and JHI and all claims of direct infringement against Pfizer are dismissible on the face of the pleadings. In short, Gelfand has stated only one legally cognizable claim, a claim against Pfizer for inducement of infringement. While this latter claim is substantively meritless, it is more appropriately addressed at a subsequent time.

III. STATEMENT OF FACTS

Except as otherwise indicated, this statement of facts is limited to the allegations of Gelfand's Counterclaim, the documents referenced therein, the uncontested allegations of Pfizer's Complaint and public information of record with the United States Food and Drug Administration ("FDA") readily available on its website.

A. The Parties

Pfizer Inc is a research-based pharmaceutical company that invents, develops, manufactures and markets leading prescription medicines for humans and animals throughout the world. Its most important product, and the world's largest selling pharmaceutical, is Lipitor®, a lifesaving cholesterol-lowering drug containing the active ingredient, atorvastatin calcium.

Complaint [D.I. 1] at ¶¶ 3, 11 (Hereinafter "Com. ¶ __"); Counterclaim at ¶ 3 (Hereinafter "Counterclaim ¶ __").[2] Lipitor® was approved for sale and marketing in the United States in 1996. (Com. ¶ 12.) Pfizer also developed, manufactures and markets a unique combination product comprised of two active ingredients, amlodipine besylate and atorvastatin calcium, which it has sold in the United States since 2004 under the registered name Caduet®. (Com. ¶¶ 13, 14.)

Dr. Jarvik is an individual residing in New York, New York who serves as President and Chief Executive Officer of JHI, a New York corporation. (Com. ¶¶ 5, 6.) Dr. Jarvik is widely respected and recognized as the inventor of the Jarvik artificial heart. (Com. ¶ 9.) Dr. Jarvik has appeared in certain of Pfizer's advertisements for Lipitor®. (Counterclaim ¶¶ 4, 32.)

Gelfand claims to be the inventor and owner of the '688 patent. (Com. ¶ 9; Counterclaim ¶¶ 9, 10.)

B. <u>This Litigation</u>

On August 5, 2005, Gelfand accused Pfizer in writing of infringing the '688 patent by reason of their activities in making, promoting and selling Lipitor® and Caduet®, threatening to seek millions in damages and an injunction against the future sale of these important, lifesaving drugs. (Com. ¶¶ 9, 10, 17, 18, 19; Counterclaim ¶¶ 28, 43.) Thereafter, on April 13, 2006, Dr. Jarvik individually entered into a two-year contract with Pfizer by which Jarvik agreed to promote Lipitor®. (Counterclaim ¶ 32.) All activity by Dr. Jarvik in advertising and promoting Lipitor® ceased on or before February 25, 2008. (*See* Ebert Aff., Exhibit C.) That same day, Gelfand provided written notice to Dr. Jarvik and JHI of their potential infringement of the '688

[2] The Complaint and Counterclaim are attached as Exhibits A and B respectively to the accompanying Affidavit of David G. Ebert, Esq. sworn to on May 16, 2008 (hereinafter "Ebert Aff.").

patent by the promotion of Lipitor® for its effects beyond cholesterol-lowering and provided a copy of a draft Complaint, threatening to bring suit within days if his demand was not met. (Counterclaim ¶ 43.)

Based upon these serious assertions of infringement, on February 28, 2008, Plaintiffs properly brought this action for declaratory judgment of non-infringement, invalidity and unenforceability against Gelfand to resolve Gelfand's accusations. On March 24, 2008, Gelfand filed: (1) Counterclaims [D.I. 6], and (2) a Motion to Dismiss the Complaint [D.I. 7], seeking to proceed solely on his Counterclaims, while asserting that the Complaint was "inconsistent with the Declaratory Judgment Act, 28 U.S.C. § 2201, et. seq." purportedly because the Complaint is "merely pre-emptive" and "procedural fencing." (Gelfand Motion to Dismiss at p. 2.) Plaintiffs opposed Gelfand's motion [D.I. 13] and filed a Motion to Dismiss and/or Strike Gelfand's Counterclaims [D.I. 15]. The Court denied Gelfand's motion on April 18, 2008 [D.I. 18] and granted Plaintiffs' Motion to Dismiss Gelfand's improperly filed Counterclaims on April 24, 2008 [D.I. 21]. Gelfand filed his Answer and Counterclaims on April 23, 2008 [D.I. 19].

C. The '688 Patent.

The United States Patent and Trademark Office issued the '688 patent on November 17, 1998, entitled "Use of Thrombolytic Reagents for Prevention of Vascular Disease," on an application, Serial Number 758,615, filed by Gelfand on November 27, 1996. (Com. ¶ 2; Counterclaim ¶ 9.) As alleged by Gelfand, the '688 patent claims only *methods* of using a drug – a process by which a thrombolytic reagent with fibrinolytic activity is chronically administered to humans in low doses over long periods of time to treat vascular disease, including cardiovascular disease and cerebral vascular disease, e.g., coronary heart disease, myocardial infarction or heart attack and stroke. (Counterclaim ¶ 10.) Claim one of the '688 patent is the only independent claim. It reads:

> A *method* for prevention of thrombotic vascular disease in a mammal, comprising the chronic administration to a patient in need thereof of an effective dose of a thrombolytic reagent to a mammal.

(Counterclaim, Exhibit "A," at 10) (emphasis added).

Gelfand asserts that:

> 11. The '688 Patent defines such thrombolytic reagents as drugs that reduce blood clots and, therefore, induce angiogenesis, *i.e.*, "drugs that act on the endogenous fibrinolytic system by converting plasminogen to the potent proteolytic enzyme plasmin. Plasmin in turn degrades fibrin clots and other plasma proteins."
> 12. The thrombolytic reagents that can be used in the practice of the '688 Patent includes "thrombolytic reagents such as tissue plasminogen activator" (t-PA) and, more broadly, all "delivery systems that provide for long-term sustained release of thrombolytic reagents, such as t-PA, in the blood, which is effective as a means for preventing the development of vascular disease."

(Counterclaim ¶¶ 11, 12.)

The '688 patent thus claims only therapeutic methods. It claims no products. It claims no methods of manufacturing products.

D. Lipitor® and Caduet®.

Lipitor® is the world's largest selling pharmaceutical and is a lifesaving cholesterol-lowering drug containing the active ingredient, atorvastatin calcium. (Com. at ¶¶ 3, 11.) By law, Pfizer was required to submit a New Drug Application for Lipitor® ("NDA") and to obtain approval of the NDA by the FDA before marketing and sale could begin. 21 U.S.C. § 355(a).[3]

Gelfand alleges that "[o]n September 30, 2003, Pfizer submitted to FDA a supplemental New Drug Application ("SNDA") for Lipitor® 'based on the Anglo-Scandinavian Cardiac Outcomes Trial (ASCOT) lipid lowering results.'" (Counterclaim ¶ 16.) Supplement 39 to

[3] This section reads in pertinent part:

> No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.

NDA 20-702 for Lipitor® submitted September 30, 2003, was approved by FDA on July 30, 2004:

> This supplemental New Drug Application provides for new indications, based upon the results of the Anglo-Scandinavian Cardiovascular Outcomes Trial Lipid Lowering Arm (ASCOT-LLA), for the use of atorvastatin in adult patients without clinically evident coronary heart disease (but with multiple risk factors for coronary heart disease such as age ≥ 55 years, smoking, hypertension, low HDL-C or a family history of early coronary heart disease), to reduce the risk of myocardial infarction, and to reduce the risk of revascularization procedures and angina. ***
> This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

http://www.fda.gov/cder/foi/appletter/2004/20702s039ltr.pdf. A copy of this FDA approval is attached to the Ebert Aff. as Exhibit D.[4] None of the approved indications for Lipitor® include the "prevention of thrombotic vascular disease" as claimed in the '688 patent. Neither the approved label[5] nor the 2003 SNDA approval of Lipitor® even mentions thrombolytic effects.

Thus, since September 30, 2003, Lipitor® has been approved by FDA and has been made and sold by Pfizer, to treat (in addition to treatment for hypercholesterolemia and other indications) adult patients without clinically evident coronary heart disease (but with multiple risk factors for coronary heart disease such as age ≥ 55 years, smoking, hypertension, low HDL-C or a family history of early coronary heart disease), to reduce the risk of myocardial infarction, and to reduce the risk of revascularization procedures and angina. The FDA approved label for Lipitor®, provided in every package of Lipitor® sold in the United States, has included this indication since September 30, 2003. (*See* Ebert Aff., Exhibit E.)

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[4] Galfand's Counterclaim pleads FDA approvals for both Lipitor® and Caduet® and necessarily relies upon these publicly available records. As such, these records are properly considered on a motion to dismiss. See *infra.* at pp. 11-12.

[5] *See* Lipitor® Label, http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory , p. 13 (Ebert Aff., Exhibit E.)

Pfizer also developed, manufactures and markets a unique combination product comprised of two active ingredients, amlodipine besylate and atorvastatin calcium, which it has sold in the United States since 2004 under the registered name Caduet®. (Com. ¶¶ 13, 14.)

Pfizer's New Drug Application for Caduet® was approved by FDA on January 30, 2004. http://www.fda.gov/cder/foi/appletter/2004/21540ltr.pdf (Ebert Aff., Exhibit F.) None of the approved indications for Caduet® include the "prevention of thrombotic vascular disease" as claimed in the '688 patent. Neither the approved label (Ebert Aff., Exhibit G) nor the 2004 FDA approval of Caduet® even mentions thrombolytic effects.

E. Dr. Jarvik's Contract with Pfizer.

On April 13, 2006, Dr. Jarvik, individually, and Pfizer entered into a personal services contract whereby Dr. Jarvik agreed, *inter alia*, to be an on camera spokesperson for and endorse Lipitor®.[6] Pursuant to this contract, Dr. Jarvik appeared in several print and broadcast ads for Lipitor®.

By the time questions were raised about Pfizer's use of Dr. Jarvik as a spokesman for Lipitor®[7], all activity by Dr. Jarvik in advertising and promoting Lipitor® had ceased.[8]

F. Gelfand's Allegations of Infringement.

Gelfand alleges that Pfizer, Dr. Jarvik and JHI have infringed the '688 patent as follows:

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[6] Gelfand pled the existence of this contract and many of its terms. (Counterclaim ¶¶ 32-37.) Redacted copies of the first and final pages of the contract are attached as Exhibit H to the Ebert Aff.

[7] *See* http://energycommerce.house.gov/Press_110/110nr148.shtml; http://energycommerce.house.gov/Press_110/110-ltr.010708.Pfizer.Jarvik.pdf (Ebert Aff., Exhibit I).

[8] New York Times, Feb. 25, 2008, http://www.nytimes.com/2008/02/25/business/25cnd-pfizer.html?em&ex=1204088400&en=bef5d1b2511bbb64%0A (Ebert Aff., Exhibit J); http://energycommerce.house.gov/Press_110/110nr210.shtml (Ebert Aff., Exhibit K).

1. **Purported Claims for Direct Infringement - 35 U.S.C. § 271(a) – All Plaintiffs.**

In his First Claim for Relief, Gelfand asserts that all Plaintiffs have directly infringed by "selling and offering to sell Lipitor® within the United States – without authority of Dr. Gelfand." (Counterclaim ¶ 47.)

In his First Claim for Relief, Gelfand also asserts that all Plaintiffs have directly infringed by "selling and offering to sell Caduet® within the United States – without authority of Dr. Gelfand." (Counterclaim ¶ 48.)

2. **Purported Claims for Direct Infringement – 35 U.S.C. § 271(a) Based on Making Lipitor® and Caduet® – Pfizer Only**

Gelfand asserts in his Fourth Claim for Relief that Pfizer has directly infringed by "making Lipitor® within the United States – without authority of Dr. Gelfand." (Counterclaim ¶ 72.)

Gelfand further asserts in his Fourth Claim for Relief that Pfizer infringes by "making Caduet® within the United States – without authority of Dr. Gelfand." (Counterclaim ¶ 73.)

3. **Purported Claims for Active Inducement - 35 U.S.C. § 271(b) – All Plaintiffs.**

In his Second Claim for Relief, Gelfand asserts that all Plaintiffs "have actively induced infringement by inducing doctors to use, prescribe, and otherwise require their patients to purchase Lipitor® within the United States – without authority of Dr. Gelfand – to secure Lipitor®'s effects beyond cholesterol-lowering, *i.e.*, as a chronically administered thrombolytic reagent in the treatment or prevention of cardiovascular disease, including heart attack and stroke." (Counterclaim ¶ 54.)

In his Second Claim for Relief, Gelfand asserts that all Plaintiffs "have actively induced infringement by inducing doctors to use, prescribe, and otherwise require their patients to purchase Caduet® within the United States – without authority of Dr. Gelfand – to secure Caduet®'s effects beyond cholesterol-lowering, *i.e.*, as a chronically administered thrombolytic reagent in the treatment or prevention of cardiovascular disease, including heart attack and stroke." (Counterclaim ¶ 55.)

4. **Purported Claims for Infringement under 35 U.S.C. § 271(e)(2) – Pfizer Only.**

Gelfand asserts in his Third Claim for Relief that Pfizer has infringed by "submitting its SNDA [for Lipitor®] of September 2003 to FDA." (Counterclaim ¶ 65), and by "submitting its NDA [for Caduet®] of 2004 to FDA." (Counterclaim ¶ 66.)

5. **Additional allegations relating to the foregoing assertions.**

Gelfand supports his infringement allegations by averring that by letter he "put Pfizer on notice that its manufacture, use, and sale of Lipitor® infringes on the '688 Patent." (Counterclaim ¶ 28.)[9] Significantly, he provides no date upon which Dr. Jarvik or JHI were put on notice of the patent, except that Gelfand alleges that he sent a letter on February 25, 2008 requesting a meeting with Jarvik. (Counterclaim ¶ 43.)

[9] It is worth noting that Gelfand incorrectly asserts that in response to this notice, Pfizer "intentionally misrepresented its promotion of Lipitor®, its September 2003 SNDA to FDA for Lipitor® and its plans for promoting Lipitor® and Caduet®" (Counterclaim ¶ 30) and that he relied to his detriment upon the misrepresentations presumably because he did not learn the full contents of the September 2003 SNDA until January 25, 2008 (Counterclaim ¶ 17). However, Gelfand could not have been misled by any statement of Pfizer. The FDA approval and the Lipitor® indications and labeling were a matter of public record, as of July 30, 2004. Thus, Gelfand's allegations of misrepresentation in a 2005 letter are false.

Gelfand further alleges that Pfizer began "a national marketing campaign for the sale of Lipitor® for its effect as a chronically administered or sustained-release thrombolytic and fibrinolytic reagent," sometime after September 2003 (Counterclaim ¶ 23) and that a material part of that marketing campaign was to induce "physicians in the United States to prescribe Lipitor®, and patients to use Lipitor®, for its effects beyond cholesterol-lowering, *i.e.*, as a chronically administered thrombolytic reagent in the treatment or prevention of cardiovascular disease, including heart attack and stroke." (Counterclaim ¶ 24.)

At no place in Gelfand's Counterclaims does he aver that Pfizer, Dr. Jarvik or JHI have themselves used the methods of the '688 patent. Nor does Gelfand allege that the methods of the '688 patent are used in the production of Lipitor® or Caduet®. Rather, the substance of Gelfand's allegations of infringement are set forth in Counterclaim paragraphs 40-42 wherein each of Pfizer, Dr. Jarvik and JHI is asserted to have from time to time:

> directly and indirectly infringed on the '688 Patent by offering for sale, selling, and inducing doctors and their patients to use Lipitor® and Caduet®, as a chronically administered thrombolytic reagent in the treatment or prevention of vascular disease, including without limitation as a chronically administered reagent for reducing or otherwise affecting blood clotting or the fibrinolytic system in patients at risk for heart disease and/or stroke.

As we explain below (with the sole exception of the allegation of inducement of infringement against Pfizer), none of the Gelfand allegations can facially withstand a motion to dismiss.

IV. ARGUMENT

A. The Standard on a Motion to Dismiss.

In deciding a motion to dismiss, a court ordinarily accepts as true all well-pleaded factual allegations and draws all reasonable inferences in favor of the non-moving party. *Flores v. S. Peru Copper Corp.*, 343 F.3d 140, 143 (2d Cir. 2003); *Levy v. Southbrook Int'l Invs., Ltd.*, 263 F.3d 10, 14 (2d Cir. 2001), *cert. denied*, 535 U.S. 1054, 122 S.Ct. 1911, 152 L.Ed.2d 821 (2002); *In re Pfizer, Inc. Securities Litigation,* 538 F. Supp. 2d 621 (S.D.N.Y. 2008). In order to survive such a motion, the non-moving party (here Gelfand) "must provide the grounds upon which his claim rests through factual allegations sufficient 'to raise a right to relief above the speculative level.' " *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007) (*quoting Bell Atl. Corp. v. Twombly*, ___ U.S. ____, ____, 127 S.Ct. 1955, 1965, 167 L.Ed.2d 929 (2007)); *see also Iqbal v. Hasty*, 490 F.3d 143, 158-59 (2d Cir. 2007) (declining to limit *Bell Atl.* holding to the antitrust context).

Moreover, "bald assertions and conclusions of law are not adequate [to state a claim] and a complaint consisting only of naked assertions, and setting forth no facts upon which a court could find a violation of the [law], fails to state a claim under Rule 12(b)(6)." *In re Tamoxifen Citrate Antitrust Litigation,* 466 F.3d 187, 200-01 (2d Cir. 2006) (citations omitted).

Review of a motion to dismiss is generally limited to the facts and allegations in the complaint alone, however, the court may take judicial notice of public records. *Blue Tree Hotels Inv., Ltd. v. Starwood Hotels & Resorts*, 369 F.3d 212, 217 (2d Cir. 2004); *Kramer v. Time Warner Inc.*, 937 F.2d 767, 773-74 (2d Cir. 1991) (SEC filings). Public Records for this purpose include records of administrative procedures. *Jeter v. New York City Dept. of Educ.*, --- F. Supp. 2d ----, 2008 WL 623135, at *3 (E.D.N.Y. 2008); *Kahn v. iBiquity Digital Corp.*, No.

06-CV-1536 (NRB), 2006 WL 3592366, at *1 n.1 (S.D.N.Y. Dec. 7, 2006) (noting that a court may consider public records and documents presented in administrative proceedings in deciding a motion to dismiss). At least one court has found FDA records and drug package inserts to be public records for this purpose. *Horne v. Novartis Pharmaceuticals Corp.*, --- F. Supp. 2d ----, 2008 WL 818819, at *5 (W.D.N.C. 2008).

Contracts not attached to a complaint but "integral" to a parties allegations are properly considered on a motion to dismiss. *International Audiotext Network, Inc. v. American Tel. and Tel. Co.*, 62 F.3d 69, 72 (2d Cir. 1995). Documents of which the non-moving party has notice, such as documents referenced but not attached to a complaint or documents attached to a motion to dismiss, can be considered without converting the motion to one for summary judgment. *See Cortec Industries, Inc. v. Sum Holding L.P.*, 949 F.2d 42, 48 (2d Cir. 1991); *Kramer v. Time Warner Inc.*, 937 F.2d 767, 773-74 (2d Cir. 1991).

B. Gelfand's First Claim For Relief Fails To State A Claim For Direct Infringement.

As stated, claim one of the '688 patent is the only independent claim. It reads:

> A *method* for prevention of thrombotic vascular disease in a mammal, comprising the chronic administration to a patient in need thereof of an effective dose of a thrombolytic reagent to a mammal.

(Counterclaim, Exhibit "A," at 10) (emphasis added).

Gelfand has failed to allege that any of the Plaintiffs have actually performed any of the *methods* claimed in the '688 patent. In his First Claim for relief, Gelfand purports to state a claim for direct infringement[10] of the '688 patent by Pfizer, Dr. Jarvik and JHI based solely upon

[10] Direct infringement is defined by 35 U.S.C. § 271(a):

the "selling and offering to sell" Lipitor® and Caduet® "within the United States – without authority of Dr. Gelfand – for" Lipitor®'s and Caduet®'s "effects beyond cholesterol-lowering, *i.e.*, as a chronically administered thrombolytic reagent in the treatment or prevention of cardiovascular disease, including heart attack and stroke." (Counterclaim ¶¶ 47 and 48.) With respect to a patent, such as the '688 patent, which claims only *methods* of use, such an allegation of sale or offer of sale manifestly fails to state a claim for direct infringement as a matter of law.[11]

Direct patent infringement occurs when a device, composition, or method that is literally covered by a patent claim or is equivalent to the claimed subject matter, is made, used, or sold by the accused party itself, without the authorization of the patent holder, during the term of the patent. *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1476 (Fed. Cir. 1998), citing 35 U.S.C. § 271(a). A method claim is directly infringed *only* when all steps of the method are performed:

> Direct infringement requires a party to perform or use each and every step or element of a claimed method or product [sic]. *Warner-Jenkinson Co., Inc. v. Hilton Davis Corp.*, 520 U.S. 17, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997) (holding that the doctrine of equivalents, like literal infringement, must be tested element by element); *Canton Bio-Med., Inc. v. Integrated Liner Techs., Inc.*, 216 F.3d 1367, 1370 (Fed. Cir. 2000); *Gen. Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1274 (Fed. Cir. 1992). For process patent or method patent claims, infringement occurs when a party performs all of the steps of the process. *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 773 (Fed. Cir. 1993).
>
> When a defendant participates in or encourages infringement but does not directly infringe a patent, the normal recourse under the law is for the court to apply the

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Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States, or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

[11] That the '688 patent consists solely of methods of use cannot be gainsaid. *See* page 10 of Exhibit "A" to Gelfand's Answer and Counterclaims: Claims 1-17 are all indisputably methods of use claims.

> standards for liability under indirect infringement. Indirect infringement requires, as a predicate, a finding that some party amongst the accused actors has committed the entire act of direct infringement. *Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1272 (Fed. Cir. 2004).

BMC Resources, Inc. v. Paymentech, L.P., 498 F.3d 1373, 1378-79 (Fed. Cir. 2007) (Rehearing En Banc Denied Feb. 11, 2008). *See also Standard Havens Products, Inc. v. Gencor Industries, Inc.*, 953 F.2d 1360, 1374 (Fed. Cir. 1991), *cert. denied*, 506 U.S. 817, 113 S.Ct. 60, 121 L.Ed.2d 28 (1992) (method claims held not directly infringed by the mere sale of an apparatus capable of performing the claimed process); *Joy Technologies, Inc. v. Flakt, Inc.*, 6 F.3d 770, 773-74 (Fed. Cir. 1993) ("The law is unequivocal that the sale of equipment to perform a process is not a sale of the process within the meaning of section 271(a)."); *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1317 (Fed. Cir. 2005) ("[u]nder section 271(a), the concept of 'use' of a patented method or process is fundamentally different from the use of a patented system or device."); *Catapano v. Wyeth Ayerst Pharmaceuticals, Inc.*, 88 F. Supp. 2d 27, 29-30 (E.D.N.Y. 2000) ("Because Catapano has not alleged that the Defendants are using or selling his method of treating immune deficient patients, he fails to state a claim for direct patent infringement under § 271(a).") *cf.*, *Embrex, Inc. v. Service Engineering Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000) ("SEC's acts of hiring Drs. Davis and Rosenberger, and the doctors' acts injecting eggs with vaccine" constituted infringement).

At no place in Gelfand's Counterclaims does he aver that Pfizer, Dr. Jarvik or JHI have actually themselves performed the methods of the '688 patent. Rather, Gelfand alleges merely that:

- sometime after September 2003, Pfizer began "marketing" Lipitor® "for its effect as a chronically administered or sustained-release thrombolytic and fibrinolytic reagent." (Counterclaim ¶ 23.)
- as early as September 2003, Pfizer actively induced infringement of the '688 patent by inducing physicians to prescribe Lipitor® "for effects beyond

cholesterol-lowering, *i.e.*, as a chronically administered thrombolytic reagent in the treatment or prevention of cardiovascular disease, including heart attack and stroke." (Counterclaim ¶ 24.)

- Dr. Jarvik entered into a contract with Pfizer for his promotion of Lipitor®, including for its "effects beyond cholesterol-lowering, *i.e.*, as a chronically administered thrombolytic reagent in the treatment or prevention of cardiovascular disease, including heart attack and stroke." (Counterclaim ¶¶ 32, 37.)
- "Since not later than April 2006, Pfizer and/or Jarvik have, directly and indirectly, urged physicians and their patients at risk for heat attack and/or stroke to use Lipitor® for its effects beyond cholesterol-lowering, *i.e.*, as a chronically administered thrombolytic reagent in the treatment or prevention of cardiovascular disease, including heart attack and stroke." (Counterclaim ¶ 39.)
- "From time to time since September 2003, Pfizer has directly and indirectly infringed on the '688 patent by offering for sale, selling, and inducing doctors and their patients to use Lipitor® and Caduet®, as a chronically administered thrombolytic reagent in the treatment or prevention of vascular disease, including without limitation as a chronically administered reagent for reducing or otherwise affecting blood clotting or the fibrinolytic system in patients at risk for heart disease and/or stroke." (Counterclaim ¶ 41.)

These allegations, at best, allege direct infringement only by third parties (patients and their doctors), not by Pfizer, Dr. Jarvik and JHI. These allegations do not aver, and cannot aver, that the sale of Lipitor® or Caduet® directly infringes the '688 method claims. Accordingly, Gelfand's First Claim for Relief must be dismissed for failure to state a claim under 12(b)(6).

C. Gelfand's Fourth Claim For Relief Fails To State A Claim For Direct Infringement By Pfizer.

Gelfand's Fourth Claim for Relief alleges Pfizer directly infringes the '688 method of use claims under 35 U.S.C. § 271(a), "by making" Lipitor® and Caduet® "within the United States – without authority of Dr. Gelfand." (Counterclaim ¶¶ 72, 73.) As stated above, "[f]or process patent or method patent claims, infringement occurs when a party performs all of the steps of the process." *BMC Resources, Inc. v. Paymentech, L.P.*, 498 F.3d at 1379 (citations omitted).

Because a method of use claim is directly infringed only when the method is performed by the accused party, the making or selling of a product *per se* cannot constitute direct

infringement. *See, e.g., Hilgraeve Corp. v. Symantec Corp.*, 265 F.3d 1336, 1342 n.2 (Fed. Cir. 2001) ("While the parties, and the district court's decision, speak of the accused devices as infringing, more properly the allegation is that the operation of the devices directly infringes the method claims at issue, or that the sale of the devices induces customers to infringe the method claims.").[12] The '688 patent contains no claims to a drug *per se* or a method of making a drug. Gelfand's Fourth Claim for Relief should be dismissed.

D. Gelfand Fails To State Any Claim Against JHI.

The sum total of the allegations against JHI in Gelfand's Counterclaims is that "[f]rom time to time since April 13, 2006, Jarvik, for his own benefit and for the benefit of JHI, has directly and indirectly infringed on the '688 patent… ." (Counterclaim ¶ 42.)

The Counterclaim states that only Dr. Jarvik entered into the professional services contract with Pfizer (Counterclaim ¶ 32) and that only Dr. Jarvik received the proceeds due under that contract. (Counterclaim ¶ 33.) The Counterclaim further avers that Dr. Jarvik reserved control of his association with Pfizer's promotion of Lipitor®. The Counterclaim also avers that only Dr. Jarvik promoted Lipitor®, nowhere stating any action taken by JHI (Counterclaim ¶ 38.)

In fact, Dr. Jarvik's contract for Pfizer was one for personal services, unrelated to Dr. Jarvik's work with JHI, and included Dr. Jarvik's truthful representation that he personally was prescribed and used Lipitor®. The most that Gelfand asserts against JHI is that it supposedly benefited from the heightened medical, media and financial attention flowing from Dr. Jarvik's promotional activities on behalf of Pfizer. Notably absent from the averments of the

[12] Gelfand has not alleged Pfizer is a contributory infringer under 35 U.S.C. § 271(c), nor could he. Lipitor® and Caduet® have substantial noninfringing uses as a cholesterol-lowering medication and 35 U.S.C. § 271(c) is inapplicable. (*See* Counterclaim ¶¶ 54, 55.)

Counterclaim is any affirmative act by JHI that could directly or indirectly infringe any claim of the '688 patent or any other patent. Gelfand's Counterclaim is based on Dr. Jarvik's actions in his personal capacity, unrelated to his status as a corporate officer of JHI.[13]

Therefore, all claims against JHI should be dismissed.

E. Gelfand Has Failed To Plead Notice Of The '688 Patent To Dr. Jarvik Or JHI Prior To The Termination Of Allegedly Inducing Activities And Therefore, Absent An Allegation Of Knowledge Of The Patent, Gelfand's Claims Under 35 U.S.C. § 271(b) For Active Inducement Fail To State A Claim.

The statute recites:

> "Whoever actively induces infringement of a patent shall be liable as an infringer."

35 U.S.C. § 271(b).

As a matter of law, inducement of infringement requires specific intent to cause direct infringement. The Federal Circuit has recently reiterated elements of inducement:

> "In order to succeed on a claim of inducement, the patentee must show, first that there has been direct infringement," and "second, that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement." *MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp.*, 420 F.3d 1369, 1378 (Fed. Cir. 2005) (*quoting Minn. Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1304-05 (Fed. Cir. 2002)). We recently clarified en banc that the specific intent necessary to induce infringement "requires more than just intent to cause the acts that produce direct infringement.... [T]he inducer must have an affirmative intent to cause direct infringement." *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) relevant section (en banc). Thus, "inducement requires evidence of culpable conduct, directed to encouraging another's infringement, not merely that the inducer had knowledge of the direct infringer's activities." *Id.*

Symantec Corp. v. Computer Associates Intern., Inc., 522 F.3d 1279, 1292-93 (Fed. Cir. 2008).

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[13] Nor can the contract between Dr. Jarvik and Pfizer be imputed to JHI in any way. *See 56 East 87th Units Corp. v. Kingsland Group, Inc.*, 30 A.D.3d 1134, 1134-35, 815 N.Y.S.2d 576 (1st Dep't. 2006) (no apparent authority and no ratification).

In his Second Claim for Relief, Gelfand has plead that Dr. Jarvik and JHI induced infringement of the '688 patent by patients and doctors by Dr. Jarvik's activities acting as a spokesperson for Lipitor® on behalf of Pfizer. However, knowledge of the existence of the patent in suit is essential to establish the specific intent to cause direct infringement. *DSU Med. Corp. v. JMS Co., supra.*; *Insituform Technologies, Inc. v. Cat Contracting, Inc.*, 161 F.3d 688, 695 (Fed. Cir. 1998) (plaintiff "cannot establish liability for inducing infringement of the '012 patent, because all accused acts by [defendant] occurred before [defendant] knew of the patent."). Without knowledge of the patent, there can be no specific intent to induce another to infringe and no knowing inducement. Gelfand has pled specifically in its Counterclaim that Pfizer was put on notice of the '688 patent on August 5, 2005 by letter. (Counterclaim ¶ 28.) Significantly absent from the Counterclaim is any assertion that Jarvik or JHI were similarly put on notice by Gelfand. Although Gelfand seeks damages from Dr. Jarvik and JHI from the date of Dr. Jarvik's personal services contract with Pfizer, April 13, 2006 (Counterclaim ¶¶ 32, 41, 42), the sole allegation that Jarvik or JHI were placed on notice of the existence of the patent is by "sending a written request for a meeting with Jarvik" and Pfizer dated February 25, 2008.[14] (Counterclaim ¶ 43.) This is also the first occasion that Pfizer was informed by Gelfand of the purported inducement of infringement by Pfizer's advertisements and of Gelfand's intention to seek damages from Dr. Jarvik for purported infringement of the '688 patent.[15] However, it is also

[14] This letter was delivered February 26, 2008.

[15] Not coincidentally, Gelfand's insertion of Dr. Jarvik into his dispute with Pfizer occurred shortly after questions were first raised publicly about Pfizer's use of Dr. Jarvik's as a spokesman for Lipitor®. On January 7, 2008, Reps. John D. Dingell (D-MI), Chairman of the Committee on Energy and Commerce, and Bart Stupak (D-MI), Chairman of the Subcommittee on Oversight and Investigations, announced that they were opening an investigation into the use of celebrity endorsements of prescription medications in direct-to-consumer advertising, specific to Dr. Robert Jarvik's appearance in Pfizer's Lipitor Commercials. *See* http://energycommerce.house.gov/Press_110/110nr148.shtml (Ebert Aff., Exhibit K);

incontestable that all activity by Dr. Jarvik in advertising and promoting Lipitor® ceased on or before February 25, 2008, before Dr. Jarvik and LHI had received Gelfand's letter. (*See* Ebert Aff., Exhibit I.)

Hence, as a matter of law, Gelfand has failed to plead a legally cognizable claim for inducement under 35 U.S.C. § 271(b). Neither Dr. Jarvik nor JHI can have induced infringement of the '688 patent without knowledge of the patent. Accordingly, Dr. Jarvik and JHI should be dismissed from Gelfand's Second Claim for Relief.

F. Gelfand Has Stated No Claim With Respect To Active Inducement By Dr. Jarvik and JHI Relating to Caduet®.

Gelfand's Second Claim for Relief alleges that each of the Plaintiffs infringed the '688 patent by actively inducing doctors to prescribe Caduet® "within the United States – without authority of Dr. Gelfand – to secure Caduet®'s effects beyond cholesterol-lowering, *i.e.*, as a chronically administered thrombolytic reagent in the treatment or prevention of cardiovascular disease, including heart attack and stroke." (Counterclaim ¶ 55.) However, the Counterclaims are specific that Dr. Jarvik endorsed only Lipitor® and engaged in no activity that could be construed as inducing infringement of the '688 patent by the use of Caduet®. In fact, Dr. Jarvik never acted as a spokesperson for Pfizer on behalf of Caduet®.

In the absence of any assertion of active inducement by Dr. Jarvik and JHI of infringement relating to Caduet®, the Second Claim for Relief should be dismissed as to Dr. Jarvik and JHI with respect to inducing infringement through the use of Caduet®.

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http://energycommerce.house.gov/Press_110/110-ltr.010708.Pfizer.Jarvik.pdf (Ebert Aff., Exhibit I).

G. Gelfand's Third Claim For Relief Fails to State a Claim Under 35 U.S.C. § 271(e)(2)(A)

By way of introduction, Gelfand's Third Claim for Relief purports to state a cause of action for infringement of the '688 patent under the "Hatch-Waxman Act," 35 U.S.C. § 271(e)(2)(A). As we explain below, Gelfand cannot state a claim for the technical infringement defined by this statute because, Gelfand has no NDA to which Pfizer seeks to refer in a 505(j) or 505(b)(2) application, the '688 patent is not listed in the FDA Orange Book as covering Lipitor® or Caduet®[16] and no certification concerning the '688 patent has been made by Pfizer (or anyone else) to the FDA. The pertinent statute, 35 U.S.C. § 271(e)(2), reads as follows (emphasis added):

> (2) It shall be an act of infringement to submit -
>
> > (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, or
> >
> > (B) an application under section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. §§ 151 - 158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent,
>
> if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

Pfizer's Lipitor® and Caduet® are not generic drugs. The applications for approval by FDA for Lipitor® and Caduet® are original New Drug Applications ("NDAs") and Supplemental NDAs under section 505(b)(1) of the Federal Food, Drug and Cosmetic Act ("FDCA").

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[16] Orange Book Patent listings for any approved drug product are readily available on-line. http://www.fda.gov/cder/ob/default.htm.

Gelfand's averment that both were 505(b)(2) applications is egregiously incorrect and contradicted by his own allegations. Gelfand's Counterclaim explicitly alleges that Pfizer filed a Supplemental New Drug Application ("SNDA") for Lipitor® (Counterclaim ¶¶ 16, 61) and NDA for Caduet® (Counterclaim ¶¶ 25, 62).[17] Gelfand's pleading is a gross distortion of 35 U.S.C. § 271(e)(2) and should be dismissed.

1. The Hatch-Waxman Amendments

The Drug Price Competition and Patent Term Restoration Act of 1984, P.L. 98 417, more commonly known as the "Hatch-Waxman Amendments," enacted a complex regulatory scheme for the pharmaceutical industry, which included 35 U.S.C. § 271(e)(2). Its purpose was to "strike a balance between 'two conflicting policy objectives: to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market.'" *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 230 (4th Cir. 2002) (citation omitted). The act of infringement contained in 35 U.S.C. § 271(e)(2) was created by section 202 of the Hatch-Waxman Amendments. A detailed discussion of the Hatch-Waxman amendments is contained in the Federal Circuit opinion in *Allergan, Inc. v. Alcon Laboratories, Inc.*, 324 F.3d 1322, 1325-27 (Fed. Cir. 2003). *See also Eisai Co., Ltd. v. Mutual Pharmaceutical Co., Inc.*, Slip Copy, 2007 WL 4556958, at *1-3 (D.N.J. 2007).

[17] A SNDA is defined by FDA as a change to an existing NDA under 505(b)(1). "A supplement number is associated with an existing FDA New Drug Application (NDA) number. Companies are allowed to make changes to drugs or their labels after they have been approved. To change a label, market a new dosage or strength of a drug, or change the way it manufactures a drug, a company must submit a supplemental new drug application (sNDA). Each SNDA is assigned a number which is usually, but not always, sequential, starting with 001." By contrast, a 505(j) or 505(b)(2) application seeks to refer to and rely on data submitted in an NDA of another, originator, party. That Pfizer has filed no such applications is incontrovertible.

Under Hatch-Waxman, a generic drug maker may seek expedited approval to market a generic version of an already-approved "pioneer" drug by submitting an Abbreviated New Drug Application ("ANDA"). *See* 21 U.S.C. § 355(j); 21 C.F.R. § 314.94 (1996). To obtain FDA marketing approval, the generic drug maker need only establish that its proposed drug is the same as the pioneer drug it imitates. An NDA applicant or holder, such as Pfizer, must provide notice of patent rights applicable to a pioneer drug through an official FDA publication titled, *Approved Drug Products With Therapeutic Equivalence Evaluations*, commonly called the "Orange Book." The Orange Book lists all commercial drug products approved for safety and effectiveness in the United States together with patents claiming the drug substances and methods of use. 21 U.S.C. §§ 355 (b)(1) and 355 (j)(7).

Under the Hatch-Waxman scheme, a generic or 505(b)(2) drug applicant must certify to the FDA that for each patent "listed" as covering the pioneer drug, the proposed generic drug would not infringe the patent because either (1) there are no applicable patents, (2) the patents have already expired, (3) that it will not be marketing before expiration of the patent, or (4) it believes that the patent is invalid or will not be infringed by its generic drug. This last certification is known as a paragraph IV certification. If the ANDA contains a paragraph IV certification, the applicant must notify the patentee, who, if it disagrees with the certification, has forty-five days to sue the ANDA applicant for infringement under 35 U.S.C. § 271(e)(2).

The act of infringement defined by § 271(e)(2) is explicitly intended to provide a case or controversy sufficient to satisfy Article III concerns so that the patentee and generic drug applicant can resolve conflicts over patent infringement and validity before a generic drug is approved by FDA. The infringement under § 271(e)(2) is intended to be a limited one:

> That is what is achieved by § 271(e)(2) – the creation of a highly artificial act of infringement that consists of submitting an ANDA or a paper NDA containing the

> fourth type of certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent.

Eli Lilly and Co. v. Medtronic, Inc., 496 U.S. 661, 678, 110 S.Ct. 2683, 2692 (1990).

2. <u>The '688 Patent has not been infringed under 35 U.S.C. § 271(e)(2).</u>

a. The '688 patent has not and cannot be listed in the FDA "Orange Book" and absent such listing, no claim of infringement is possible under 35 U.S.C. § 271(e)(2)

The artificial act of infringement defined in 35 U.S.C. § 271(e)(2) cannot be understood, except within the framework of the entire Hatch-Waxman Amendments. Congress never intended to establish a stand-alone act of infringement unrelated to a generic drug attempting to enter the market by relying upon the safety and effectiveness proven for the pioneer drug. Gelfand's Third Claim for Relief does not allege that Pfizer submitted a generic drug application for Lipitor® or Caduet®. Gelfand cannot make such an allegation. Gelfand has no NDA to which Pfizer could refer in filing under 505(j) or 505(b)(2). Both Lipitor® and Caduet® were approved by FDA based upon New Drug Applications for which Pfizer conducted the expensive and time consuming clinical trials required for FDA approval. Moreover, Gelfand cannot and does not aver that the '688 patent is listed in the Orange Book. Nor does Gelfand aver that Pfizer filed any certification with FDA regarding the '688 patent. Therefore, none of the necessary predicates to infringement under 35 U.S.C. § 271(e)(2) have occurred or are even alleged to have occurred by Gelfand. The act of infringement alleged by Gelfand, if allowed to stand, would be entirely divorced from the purpose and intention of the Hatch-Waxman Amendments.

It is clear that no infringement under 35 U.S.C. § 271(e)(2) occurs unless and until an ANDA (505(j)) or a paper NDA (505(b)(2)) containing a Paragraph IV certification is filed with FDA. *Eisai*, 2007 WL 4556958, at *11 ("according to the Federal Circuit, § 271(e)(2) depends upon the filing of an ANDA containing a Paragraph IV certification."). The *Eisai* court

conducted a complete review of the statutory history and the case law interpreting it. The court concluded:

> Thus, this Court holds that to establish an act of infringement pursuant to § 271(e)(2), the ANDA must contain a Paragraph IV certification against a patent listed in the Orange Book for the drug in question. Here, Mutual's ANDA contained no such certification. Therefore, Eisai cannot bring a claim pursuant to § 271(e)(2).

Id. at *12.

Gelfand can make no allegation that a paragraph IV certification was filed for the '688 patent or that the '688 patent was ever listed in the Orange Book for Lipitor® or Caduet®. Accordingly, he has no claim under 35 U.S.C. § 271(e)(2).

We hasten to add that Gelfand's frivolous claim of infringement under 35 U.S.C. § 271(e)(2) is totally superfluous. He has pled infringement under 35 U.S.C. § 271(a) and (b). The jurisdictional hook of 35 U.S.C. § 271(e)(2) is thus unnecessary and irrelevant because (if Lipitor® and Caduet® infringe or induce infringement of the '688 patent, which they do not) it is not disputed that actual sales of these products have occurred. Attempting to force the present dispute into the artificial act of infringement of 35 U.S.C. § 271(e)(2) is both frivolous and pointless.

Gelfand has not stated a claim for relief under 35 U.S.C. § 271(e)(2) and his Third Claim for Relief must be dismissed.

b. Even if Gelfand could state a claim for relief under 35 U.S.C. § 271(e)(2), the conclusory allegation of a "505(b)(2)" submission is contrary to the incontrovertible facts.

The act of infringement defined by § 271(e)(2)(A) requires an application under section 505(j) or 505(b)(2) of the Federal Food, Drug and Cosmetic Act ("FDCA"). Gelfand explicitly and falsely alleges that Pfizer's Lipitor® and Caduet® applications "constitute[s]" section

505(b)(2) applications.[18] (Counterclaim ¶¶ 63, 64.) Despite this conclusory allegation, it is clear from the irrefutable public records of the FDA that neither the Lipitor® nor Caduet® applications constituted a 505(b)(2) application. They are 505(b)(1) "NDA" and "SNDA" applications.[19] *See supra*, pp. 20-21. Thus, Gelfand's 35 U.S.C. § 271(e)(2) claim is dismissible for this additional reason.

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[18] Since Gelfand pled that he received a copy of the September 30, 2003 SNDA under the Freedom of Information Act (Counterclaim ¶ 17), he cannot be heard to deny the facts contained therein.

[19] A section 505(b)(2) application is one that contains full investigations of safety and effectiveness but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. This is also known as a so called "paper New Drug Application" ("paper NDA"). Like ANDA's, paper NDA's permit an applicant seeking approval of a generic drug to avoid the costly and time-consuming studies required for a pioneer drug, *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 676, 110 S.Ct. 2683, 2692 (1990), by relying upon published studies or on prior FDA determinations of safety and effectiveness.

Only those paper NDAs which refer to a previously approved drug are subject to exclusivity rights. Thus, if A is a pioneer and B files a paper NDA, the court looks to whether B referred in its application to the work performed by A. If B did not so refer, then B does not become barred by the pioneer A's assertion of exclusivity under the amended FDCA. *Burroughs Wellcome Co. v. Bowen*, 630 F. Supp. 787 (E.D. N.C. 1986); and the paper NDA process was less useful after the 1984 amendments, *see* 57 Fed. Reg. 17950-51 (Apr. 28, 1992), 1 Food and Drug Admin. § 13:172 (2007).

Importantly, paper NDA applications must include patent certifications described at 21 § C.F.R. 314.50(i) and must provide notice of certain patent certifications to the NDA holder and patent owner under 21 C.F.R. § 314.52.

V. CONCLUSION

Once again, Gelfand has needlessly multiplied these proceedings by the assertion of frivolous claims. For the reasons set forth above, Plaintiffs' Motion to Dismiss Defendant's Counterclaims should be granted.

Respectfully Submitted,

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